IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

THE UNITED STATES OF AMERICA *ex rel.* JESSE M. POLANSKY, M.D., M.P.H.,

Plaintiff,

v.

GEISINGER HOLY SPIRIT; GEISINGER COMMUNITY MEDICAL CENTER; GEISINGER MEDICAL CENTER; SPIRIT PHYSICIAN SERVICES INC.

Defendants.

Civil Action No. 1:20-cv-00599
(Judge Conner)

Leave to File Excess Pages Granted (Dkt. 77)

Oral Argument Requested

BRIEF IN SUPPORT OF THE DEFENDANTS' MOTION TO DISMISS THE AMENDED COMPLAINT

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I. INTRODUCTION AND SUMMARY OF ARGUMENT

Dr. Jesse Polansky is a serial but unsuccessful *qui tam* relator. The circumstances and outcome of his most recent *qui tam* litigation give rise to several of the grounds on which the Court should dismiss the present case.

Polansky filed his first *qui tam* in the Southern District of New York against a global pharmaceutical company. The Government investigated but declined to intervene, the court dismissed the case for failure to state a claim, and the Second Circuit affirmed.[1] He filed his second *qui tam*—which is directly relevant to the present motion—in the Eastern District of Pennsylvania ("*Polansky I*").[2] He alleged that a medical billing consultant, Executive Health Resources ("EHR"), caused Geisinger Holy Spirit and all of EHR's other hospital-clients to submit false claims. Dkt. 428-3 at ¶¶ 2, 277 and n. 19. Polansky's theory was that EHR caused hospitals to misclassify patients as inpatients rather than outpatients or under observation status. *Id.*

Polansky I did not go well for Polansky. The Government investigated his allegations but declined to intervene. Dkt. 19. The court granted a motion to dismiss the claims against the two hospitals Polansky named as defendants. Dkt. 103. Eventually, the court sanctioned Polansky for failing to timely produce 14,000

[1] *United States ex rel. Polansky v. Pfizer, Inc.*, 822 F.3d 613 (2d Cir. 2016).

[2] *United States ex rel. Polansky v. Executive Health Resources*, No. 2:12-cv-04239-MMB (E.D. Pa). "Dkt." citations in this brief refer to the docket in *Polansky I*, unless otherwise noted. True and correct copies of these and all other materials of which the Defendants request judicial notice are included in an appendix filed with this brief.

documents that he took—without permission—shortly before his employment was terminated by a government agency, the Centers for Medicare & Medicaid Services ("CMS"). Dkt. 400; Dkt. 561 at 4. Soon thereafter, the Government exercised its power to dismiss the case altogether, with prejudice as to Polansky. In determining that the Government had good cause to dismiss the case, the court analyzed the merits of Polansky's claims, and also ruled that his explanation about the pilfered documents was "not completely credible" and his "behavior was material and plays a role in the final disposition of this case." Dkt. 561 at 4. The Supreme Court granted certiorari, and issued a ruling last year that affirmed the judgment dismissing the case. *United States ex rel. Polansky v. Exec. Health Res., Inc.*, 599 U.S. 419 (2023).

This brings us to the present case, *Polansky II*. In 2020, while *Polansky I* was pending on appeal, Polansky sued Geisinger Holy Spirit, two other hospitals (Geisinger Community Medical Center and Geisinger Medical Center), and an affiliated physician group (Spirit Physician Services Inc.).[3] AC ¶ 1.[4] At the core of this case is an allegation that the "Defendants conspired with their billing vendor, EHR" to submit false claims

[3] We follow Polansky's convention and refer to the three hospitals together as the "Hospital Defendants" and all defendants together as the "Defendants." For brevity, we refer to Geisinger Holy Spirit as "Holy Spirit"; Geisinger Community Medical Center as "Community Medical Center"; Geisinger Medical Center by that name; and Spirit Physician Services Inc. as "Spirit Physician Services."

[4] "AC" citations and references to the "complaint" refer to Polansky's amended complaint in the present case, No. 1:20-cv-00599-CCC at Dkt. 73. "OC" citations refer to the original complaint (Dkt. 1).

based on the same inpatient/outpatient/observation-status theory in *Polansky I*. AC ¶ 192. Conceding the overlap with *Polansky I*, Polansky alleges here that "all the Hospital Defendants" were "standard EHR hospital client[s]" and they acted "[l]ike all EHR client hospitals." AC ¶¶ 19, 135. Indeed, many of his allegations are cut-and-pasted from *Polansky I*. As with Polansky's earlier cases, the Government declined to intervene as plaintiff after investigating Polansky's allegations. *Polansky II*, Dkt. 31.

After the Defendants moved to dismiss Polansky's original complaint, Polansky filed an amended complaint. For the most part, the amended complaint narrows Polansky's theories and the dates of the alleged violations, although he has added a new count under the Stark Act, 42 U.S.C. § 1395nn. The Defendants now move to dismiss the amended complaint on nine independent grounds:

First, the government-action bar in the False Claims Act provides that "[i]n no event may a person bring" a new case "based upon allegations or transactions which are the subject of a civil suit ... in which the Government is already a party." 31 U.S.C. § 3730(e)(3). As set out below, this case is plainly based on the same allegations and transactions described in *Polansky I*. And in its ruling on *Polansky I*, the Supreme Court held that the Government was a party to *Polansky I*. *See Polansky*, 599 U.S. at 432–33. Accordingly, this action is barred. This is straightforward and outcome-determinative, and the Court need go no further on the eight arguments that follow—it should dismiss the case, with prejudice, on this basis.

Second, the first-to-file rule in the False Claims Act bars relators from filing new

cases "based on facts underlying [another] pending action." 31 U.S.C. § 3730(b)(5). Because *Polansky I* was pending when Polansky filed the present case, and this case is based on the facts underlying the first case, it must be dismissed. The amended complaint does not cure this problem.

Third, collateral-estoppel principles bar Polansky from relitigating the same EHR theory that the court dismissed with prejudice in *Polansky I*. The Supreme Court noted that an assessment of the merits was part of the Government's justification for dismissing *Polansky I*. 599 U.S. at 433, 438. The district court in *Polansky I* said the same thing. Dkt. 561 at 7, 16. Furthermore, the district court earlier dismissed Polansky's claims against two other hospitals based on his EHR theory, long before the Government moved to dismiss the case—that ruling was certainly on the merits, and it was not appealed. *See* Dkt. 103. Collateral estoppel bars the theory at the heart of this case, requiring that the Court dismiss the case.

Fourth, apart from exceptions that are not applicable here, the False Claims Act has a six-year statute of limitations. 31 U.S.C. § 3731(b)(1). This case was filed on April 10, 2020, so any claims for alleged violations prior to April 10, 2014 are barred. Polansky appears to concede this point, as his amended complaint now limits his claims to 2014 and later. But there is another (and uncured) facet to this problem. Polansky—who left his job at Holy Spirit in May 2014—has not pleaded any facts or specifics to suggest a strong inference (as required under Federal Rule of Civil Procedure 9(b)) that any false

claims were submitted during the limitations period. Thus, the amended complaint should be dismissed for failure to plead any violations within the statute of limitations.

Fifth, Polansky's new claim under the Stark Act fails as a matter of law. As shown below, the physician compensation arrangement in question is commonplace and does not violate the Stark Act.

Sixth, Polansky's claims from prior to when a provision known as the "Two-Midnight Rule" was codified in 2013 fail under *Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019), because they are based on non-controlling guidance (a CMS Manual). And as noted above, these pre-2013 claims are outside the statute of limitations.

Seventh, Polansky argues that starting in 2013, the Hospital Defendants violated the codified Two-Midnight Rule by coding patients upon admission based on how sick they were and their risk of adverse events, rather than only based on the number of midnights that they were expected to be in the hospital. *See* AC ¶ 5 (alleging false claims because the hospitals used "a purported assessment of risk, rather than expected duration"). But these are two sides of the same coin: nothing prohibits doctors from considering how sick patients are in determining how long they are likely to be in the hospital. Indeed, the codified Two-Midnight Rule says that doctors *should* consider "complex medical factors as patient history and comorbidities, the severity of signs and symptoms, current medical needs, *and the risk of an adverse event*." 42 C.F.R. § 412.3(d)(1)(i) (emphasis added). It even says that where a doctor does *not* expect that a patient's care will cross two midnights, inpatient status may nevertheless be

appropriate based on "clinical judgment," "severity of signs and symptoms," and "risk of an adverse event." *Id.* at § 412.3(d)(3). Yet Polansky alleges that the Hospital Defendants violated the False Claims Act by taking into account how sick patients were and their risk of an adverse event. This is one of many examples where Polansky's personal views about billing rules differ from the law.

Eighth, Polansky has not pleaded facts to show materiality as required under *Universal Health Servs., Inc. v. United States*, 136 S. Ct. 1989 (2016) ("*Escobar*"). The Government has been on notice of Polansky's EHR theory for twelve years—i.e., since he filed *Polansky I* in 2012—yet he does not allege that it stopped paying claims because a hospital used EHR's tools. Under *Escobar,* this is "very strong evidence" suggesting no materiality, *id.* at 2003, and Polansky has not pleaded facts to suggest materiality. Furthermore, as *Polansky I* held, the Government's conduct (all of which is subject to judicial notice) belies any notion of materiality. It investigated *Polansky I* but declined to intervene as plaintiff. It even exercised its authority to dismiss that case altogether, preventing Polansky from enforcing the supposedly material requirements in question. It investigated the theory again in *Polansky II*, and again declined to intervene.

Ninth, and finally, the amended complaint fails to provide the details and specifics required under Federal Rule of Civil Procedure 9(b). As to two of the three Hospital Defendants—Geisinger Medical Center and Community Medical Center—it provides almost no specifics at all. For example, as to Geisinger Medical Center,

Polansky alleges only that the hospital contracted with EHR "sometime between 2011 and 2014," and it was an "enthusiastic" customer of EHR—that is it. AC ¶¶ 92, 137.

Accordingly, the Court should dismiss the amended complaint. Because Polansky has already amended his complaint, and because many of the grounds for dismissal could *never* be cured through amendment, the Court should dismiss the case with prejudice (as to Polansky) and without leave to amend. Twelve years of litigation on Polansky's failed EHR theory is enough.

II. STATEMENT OF QUESTIONS PRESENTED

1. Did Polansky violate the government-action bar?

2. Did Polansky violate the first-to-file bar?

3. Does collateral estoppel bar Polansky's EHR theory?

4. Has Polansky pleaded facts to show any violations within the statute of limitations?

5. Has Polansky pleaded facts required to show a Stark Act violation?

6. Has Polansky failed to state a claim and plead sufficient details as to his False Claims Act counts arising before the Two-Midnight Rule?

7. Has Polansky failed to state a claim and plead sufficient details as to his False Claims Act counts arising after the Two-Midnight Rule?

8. Has Polansky failed to plead facts showing materiality under the False Claims Act?

9. Has Polansky failed to plead specifics to support a strong inference that each Defendant violated the law?

III. FACTS AND PROCEDURAL BACKGROUND

A. The parties

1. Polansky

Polansky is a *qui tam* relator and filed this case purportedly on behalf of the United States. AC ¶ 27.

During his career, Polansky has moved briskly between employers, leaving a wake of *qui tam* complaints and other legal disputes behind him, mostly after very short periods of employment. *See* AC ¶¶ 29–37. According to his first *qui tam* complaint, he worked for Pfizer from 2001 until he was terminated in 2003. *See U.S. ex rel. Polansky v. Pfizer, Inc.*, No. 04-CV-0704, 2009 WL 1456582, at *1 (E.D.N.Y. May 22, 2009). Polansky then went to work for the Government at CMS. AC ¶ 37. In *Polansky I,* Polansky described how he left CMS under a "settlement agreement" that he asserted was confidential. Dkt. 257. He claimed this agreement, which he refused to produce in *Polansky I*, "expunged" certain facts and documents, and apparently meant that he did not have to disclose the facts or produce the documents in discovery. *Id.*

Next, Polansky worked for EHR for 61 days in late 2011 and early 2012, until he was fired. AC ¶¶ 10, 29. He then worked for a private Medicare audit contractor for less than a year. *Id.* ¶ 30. Polansky then joined Holy Spirit Health System, a health system including Holy Spirit, where he worked as a physician advisor from in or around

December 2013 to May 2014 when "his position was eliminated." *Id.* ¶¶ 31–32. He left before Holy Spirit became an affiliate of Geisinger Health, which he describes as the health system of which the Defendants are part. *Id.* ¶ 32. After leaving Holy Spirit, he worked for a few months at a Maryland Medicaid contractor, and then for a few months at Summit Health (another EHR client) in 2015. *Id.* ¶¶ 34, 35.

2. The Defendants

The Defendants are non-profit health care entities, and were part of the Geisinger Health system during some but not all of the period relevant to the present dispute. AC ¶¶ 38-41.

Holy Spirit is a non-profit hospital in Camp Hill, Pennsylvania. *Id.* ¶ 38. Polansky alleges that Holy Spirit became an EHR client in 2010. *Id.*¶ 59. Holy Spirit became part of Geisinger Health in 2014. *Id.* ¶ 32. Spirit Physician Services was a non-profit organization affiliated with Holy Spirit "that manages primary care and specialty physician services." *Id.* ¶ 41.[5]

Community Medical Center is a non-profit hospital in Scranton, Pennsylvania. *Id.* ¶ 39. Polansky alleges that Community Medical Center was an EHR client starting in 2010. *Id.*¶ 59. Community Medical Center became part of Geisinger Health in 2012. *Id.* ¶ 33. Polansky does not allege that he worked for Community Medical Center.

[5] Holy Spirit and Spirit Physician Services are no longer part of Geisinger Health. AC ¶ 38.

Geisinger Medical Center is a non-profit hospital in Danville, Pennsylvania that is part of the Geisinger Health system. *Id.* ¶ 40. Polansky alleges that this entity was an EHR client "by at least 2014." *Id.* ¶ 59. Polansky does not allege that he worked for Geisinger Medical Center.

B. Relevant health care programs and billing rules

Polansky alleges that the Defendants submitted false claims to several federal health care programs, specifically Medicare, Medicare Advantage, and TRICARE. *Id.* ¶ 2. He also alleges claims relating to Pennsylvania's Medicaid program. *Id.*

This case is about the standards under which doctors admit patients to the hospital. There are three relevant statuses: inpatient, observation, and outpatient. AC ¶ 3. As Polansky alleges repeatedly, classification as inpatient or observation status does not change the services or quality of care a patient receives—it only affects billing and reimbursement. *See, e.g.*, AC ¶¶ 5, 73.

There are two periods relevant to Polansky's allegation: before and after the Government enacted a codified rule known as the Two-Midnight Rule. Prior to October 2013, there was no statute or formal regulation that provided criteria for hospitals to determine whether inpatient status was appropriate. Instead, sub-regulatory guidance, such as the Medicare Benefit Policy Manual, suggested factors physicians should consider in determining hospital status. *See* AC ¶¶ 98, 101 (citing Manual).

The second period is after the Two-Midnight Rule went into effect. As of October 1, 2013, a requirement of formal inpatient admission was codified at 42 C.F.R.

§ 412.3(a). 78 Fed. Reg. 50496, 50965 (Aug. 19, 2013). The rule emphasizes that decisions are to be made "based on the clinical judgment of the admitting physician" and "based on such complex medical factors as patient history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event." 80 Fed. Reg. 70298, 70541 (Nov. 13, 2015). Taking these factors into account, doctors are to consider whether a patient is likely to need to be in the hospital for two or more midnights.

Importantly, this analysis is made prospectively, upon admission, based on the doctor's analysis at the time—not based on how long the patient actually spends at the hospital. *See* 42 C.F.R. § 412.3(a). Polansky admits this: "[t]he actual length of stay is not the deciding factor." AC ¶ 100. Furthermore, the rule acknowledges that even "[w]here the admitting physician expects a patient to require hospital care for only a limited period of time that does not cross 2 midnights, an inpatient admission may be appropriate for payment" nonetheless "based on the clinical judgment of the admitting physician…." *Id.*

C. *Polansky I*

On July 26, 2012, Polansky filed a *qui tam* complaint against EHR. *See generally* Dkt. (reflecting case filing date). His second amended complaint also pleaded claims against two hospitals (Yale-New Haven Hospital, Inc. and Community Hospital of the Monterey Peninsula) that he alleged were EHR clients. *See* Dkt. 101. After investigating, the Government declined to intervene. Dkt. 19.

EHR, its parent companies, and the two hospitals moved to dismiss. The court granted and denied these motions in part, dismissing the state-law claims against EHR, all claims against the parent companies, and all claims against the two hospitals. Dkt. 94, 103.

After several years of contentious discovery, Polansky filed a "supplement" to his second amended complaint and eventually a third amended complaint. Dkt. 173-2; Dkt. 428-3. As discussed below, both the supplement and the third amended complaint contained extensive allegations about Holy Spirit. *Id.*

On August 20, 2019, the Government moved to dismiss Polansky's case pursuant to 31 U.S.C. § 3730(c)(2)(A). Dkt. 526. On September 26, 2019, the court notified the parties that it was considering granting summary judgment *sua sponte* against Polansky on the merits. Dkt. 550. After the parties briefed these issues, the court issued a memorandum and order on November 5, 2019 granting the Government's motion to dismiss under § 3730(c)(2)(A), granting summary judgment to the defendants as to pre-Two-Midnight-Rule claims, and stating (without formally ruling) that "lack of materiality under *Escobar* may warrant summary judgment" as to all claims as "[t]here is no evidence that CMS ever ... refused to pay a reimbursement claim that [EHR] certified." Dkt. 561 at 3.

Polansky appealed to the Third Circuit, which affirmed the § 3730(c)(2)(A) dismissal. *Polansky v. Exec. Health Res. Inc*, 17 F.4th 376, 393 (3d Cir. 2021). Polansky did

not appeal the lower court's ruling granting the hospitals' motion to dismiss in 2014, and accordingly, that ruling is undisturbed. *Id.* at 381 n.3.

The Supreme Court granted certiorari to address the standard the Government must meet under § 3730(c)(2)(A) to dismiss a case after earlier declining to intervene. The Court rejected the Government's argument that it can dismiss a case *without* also intervening for the purpose of dismissal. 599 U.S. at 430. Instead, it held that the Government must show "good cause" to intervene, at which point it would become a party, and it could then dismiss the case. *Id.* at 427–30. As the Government had properly intervened as a party in *Polansky I* to dismiss the case, the Court "affirm[e]d in all respects the judgment below." *Id.* at 439.

D. *Polansky II*

Polansky filed the present case—*Polansky II*—on April 10, 2020. *See* Dkt. 1. The Hospital Defendants cooperated with the Government's investigation of these allegations. The case remained under seal until the Government announced its decision to decline to intervene on November 27, 2023. *Polansky II*, Dkt. 31.

After the Defendants moved to dismiss, Dr. Polansky filed an amended complaint on April 29, 2024. The amended complaint makes only modest changes from the original complaint. The relevant changes eliminate claims based on alleged violations prior to 2014 (*see e.g.*, OC ¶ 2 and AC ¶ 2; OC ¶ 89 and AC ¶ 88; OC ¶ 186 and AC ¶ 184; OC ¶ 187 and AC ¶ 185); remove allegations that the Defendants violated the False Claims Act by improperly billing patients under observation status

when they should have been billed as outpatients; remove the claim under the Anti-Kickback Statute; and add a claim under the Stark Act.

E. The substantial overlap between *Polansky I* and *Polansky II*

Polansky has been litigating against EHR and its clients for twelve years. There is extensive overlap between *Polansky I*, where Polansky discussed and relied on Holy Spirit's use of EHR's services to support his claim against EHR, and *Polansky II* where he sued Holy Spirit and the other affiliated Hospital Defendants on the same allegations.

As the district court in *Polansky I* explained, the "core … theory of liability" in that case was "that [EHR] exploited the difference in reimbursement rates for inpatient and outpatient services, causing hundreds of thousands of claims for medical services to be billed as inpatient when they should have been billed as outpatient." Dkt. 561 at 2. There, Polansky alleged "a nationwide scheme to defraud Medicare and Medicaid engineered by [EHR] … with approximately 2,400 hospitals in 50 states using its services." Dkt. 428-3 ¶ 2. Similarly, in the present case, Polansky alleges that "[d]efendants conspired with their billing vendor, EHR, and their treating physicians to defraud the Government…" based on the use of the same EHR billing analysis, and that the Hospital Defendants acted exactly the same as EHR's other hospital-clients. AC ¶¶ 19, 135, 142, 192.

While far from comprehensive, the chart below illustrates some of the common factual allegations and legal theories on which both cases are based:

Allegation	*Polansky I*	*Polansky II*
All of EHR's client hospitals use the same process regardless of payor and EHR's advisors use the same process for each client.	Dkt. 428-3 ¶¶ 84, 109-110.	AC ¶¶ 19, 135.
EHR clients relied upon and adopted EHR's "fraudulent" policies and practices.	Dkt. 428-3 ¶ 3.	AC ¶¶ 4, 77.
EHR's policies were "fraudulent" because they focused on how sick patients were and their risk of adverse events, not merely the anticipated length of stay.	Dkt. 428-3 ¶ 122.	AC ¶ 5.
EHR clients knew or recklessly disregarded that adoption of EHR's recommendations led to false claims.	Dkt. 428-3 ¶ 234.	AC ¶ 131.
EHR clients falsely certified compliance through submission of Form CMS-1450.	Dkt. 428-3 ¶¶ 214, 235, 327.	AC ¶ 121.
EHR uses fake science or fraudulent criteria to determine hospital status.	Dkt. 428-3 ¶ 305.	AC ¶ 70.
EHR's approach results in false claims because it suggests different results than McKesson's InterQual product.	Dkt. 428-3 ¶¶ 87-88, 227–29.	AC ¶¶ 85–86.
EHR certifications were determinative of billing status for EHR clients.	Dkt. 428-3 ¶ 310.	AC ¶ 142.
EHR clients improperly delegated their UR function to EHR.	Dkt. 428-3 ¶ 106.	AC ¶ 105.
Holy Spirit did not maintain a compliant UR plan or functioning UR Committee.	Dkt. 428-3 ¶ 310.	AC ¶ 105.

Although *Polansky I* did not list Holy Spirit as a party, it identified Holy Spirit by name and included verbatim many of the allegations against it present here. While again far from comprehensive, a side-by-side comparison of the allegations in each case leaves little room for doubt that Polansky recycled allegations from the earlier case:

Polansky I	*Polansky II*
"Beginning in or around December 2013, and continuing through May 2014, Dr. Polansky was employed by Holy Spirit Health System ('Holy Spirit'), a health system including a 300-bed community hospital located near Harrisburg, Pennsylvania, as its Chief Physician Advisor." Dkt. 428-3 ¶ 277.	"Beginning in or around December 2013, and continuing through May 2014, Dr. Polansky was employed by Holy Spirit Health System, a health system including Holy Spirit Hospital, a 300-bed community hospital located near Harrisburg, Pennsylvania, as its Chief Physician Advisor." AC ¶ 31.
"Dr. Polansky's duties involved leading efforts to ensure that Holy Spirit correctly assigned hospital status (*i.e.*, inpatient vs. outpatient) for billing purposes." Dkt. 428-3 ¶ 277.	"One of Dr. Polansky's primary duties involved leading efforts to ensure that Holy Spirit correctly assigned hospital status for its commercial health insurance clients." AC ¶ 31.
"Dr. Polansky was also tasked with reviewing EHR's performance under its Medicare and Medicaid contract with Holy Spirit. In the course of that work, Dr. Polansky conducted a retrospective review of cases, including a range of Medicare short-stay medical and minor procedure cases which EHR had certified as inpatient. The cases reviewed by Dr. Polansky represented time periods both before and after CMS's August 2013 adoption of the 'Two Midnight Rule.'" Dkt. 428-3 ¶ 278.	"Dr. Polansky was tasked with reviewing EHR's performance under its contract with Holy Spirit to provide concurrent review and appeal services for traditional Medicare and Pennsylvania Medical Assistance. In the course of that work, Dr. Polansky conducted and shared with Geisinger Holy Spirit's executives on April 30, 2024 a comprehensive review of EHR's concurrent review and appeals services. This included reviewing short-stay emergent and elective cases which EHR had certified as meeting Medicare requirements for inpatient and observation services. The cases reviewed by Dr. Polansky represented time periods both before and after his joining Geisinger Holy Spirit." AC ¶ 146.

Polansky I	*Polansky II*
"However, during the period of Dr. Polansky's employment, Holy Spirit did not maintain a functioning UR Committee. Instead, Holy Spirit effectively delegated the UR Committee's oversight and review functions to EHR's physician advisors, who made the final decisions on hospital status." Dkt. 428-3 ¶ 310.	"The Hospital Defendants, like all EHR client hospitals that adopted EHR's policies and practices, violated these rules by delegating their Utilization Review obligations to EHR. In fact, when Dr. Polansky joined Geisinger Holy Spirit there was no operating UR Committee and he was told there had been no committee for some time. He was told by his management that the UR Committee was not necessary given the EHR contract." AC ¶ 105.
"EHR provided an inpatient certification on May 8, 2012, and Holy Spirit billed the claim for inpatient services to Medicare, with the result that EHR's false certification caused Holy Spirit to submit a false claim for inpatient services from Medicare." Dkt. 428-3 ¶ 319.	"EHR provided an inpatient Certification on May 8, 2012, and Geisinger Holy Spirit billed the claim for inpatient services to Medicare." AC ¶ 154.
"Dr. Polansky was not the only member of Holy Spirit's executive staff to question recognize [sic] the falsity of EHR's certifications. Dr. Polansky, as part of his responsibilities, discussed EHR certifications that illustrated his concerns about EHR's violations of Medicare requirements with the hospital's Chief Medical Officer, Chief Compliance Officer, and ultimately with the Chief Financial Officer." Dkt. 428-3 ¶ 320.	"Dr. Polansky was not the only member of Geisinger Holy Spirit's executive staff to communicate and recognize that relying on EHR's medical necessity Certifications, policies, and practices failed to comply with applicable law. Dr. Polansky, as part of his responsibilities, discussed and documented ongoing concerns about systemic violations of Medicare requirements with the hospital's Chief Medical Officer, Chief Compliance Officer, Director of Utilization Management, and ultimately with the Chief Financial Officer." AC ¶ 138.

Polansky I	*Polansky II*
"During a February 19, 2014 discussion of an EHR certification for a Medicare patient with chest pain, the Chief Medical Officer commented that the EHR inpatient certification was "useless" and that EHR created "more compliance risk in this case" than the entirety of another billing program also known to be a compliance risk. Similarly, the Chief Compliance Officer stated that she did not "see anything acute" (i.e., warranting inpatient status in the case under discussion), and that she understood why her colleagues (i.e., compliance officers at other hospitals) were 'all cancelling EHR contracts,' specifically mentioning Dr. Polansky's future employer, Summit Health." Dkt. 428-3 ¶ 320.	"During a discussion on or around February 19, 2014 about an EHR certification for a Medicare patient with chest pain, the Chief Medical Officer commented that EHR inpatient certifications were 'useless' and that EHR created 'more compliance risk' than another vendor program that Holy Spirit was using to optimize coding of patient severity to increase hospital payments (a similar practice by Medicare Advantage plans is currently under investigation by the Department of Justice). Similarly, the Chief Compliance Officer stated that she did not 'see anything acute' (*i.e.,* warranting inpatient status) in the case under discussion, and that she understood why her colleagues *(i.e.,* compliance officers at other hospitals) were 'all cancelling EHR contracts,' specifically mentioning Dr. Polansky's future employer Summit Health." AC ¶ 141.
"This was confirmed by Holy Spirit's Director of Hospitalists, who told Dr. Polansky on February 19, 2014 that "we follow EHR recs 100% of the time – they are the experts." She also told Dr. Polansky that her hospitalist team did not have concerns about deferring to EHR's expertise in assigning hospital status because it did not impact the care of the patient." Dkt. 428-3 ¶ 325.	"This was confirmed by Geisinger Holy Spirit's Director of Hospitalists, who told Dr. Polansky on February 19, 2014 that 'we follow EHR 100% of the time and have adopted EHR's risk-based determination of hospital status.' She also told Dr. Polansky that her hospitalist team did not have concerns about deferring to EHR's policies and practices because they did not impact the scope or intensity of clinical care of the patient." AC ¶ 142.

IV. LEGAL STANDARD

The Court must dismiss a complaint that "fails to state a claim on which relief may be granted." Fed. R. Civ. P. 12(b)(6). Because the False Claims Act is an anti-fraud statute, Polansky's complaint must satisfy both Rule 8's plausibility standard as well as

Rule 9(b)'s heightened particularity requirement. *United States ex rel. Petras v. Simparel, Inc.*, 857 F.3d 497, 502 (3d Cir. 2017).

Under Rule 8, a complaint must state a "plausible claim for relief." *Id.* (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). A claim is plausible only when it contains sufficient factual allegations for the court "to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. The plausibility standard demands "more than a sheer possibility that a defendant has acted unlawfully." *Id.* Thus, "[w]here a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility.'" *Id.* (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557 (2007)). Legal conclusions and recitations of claim elements are not enough. *Iqbal*, 556 U.S. at 678 ("Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.").

Under Rule 9(b)'s heightened pleading requirements, Polansky "must state with particularity the circumstances constituting fraud." *Petras*, 857 F.3d at 502. In this context, this requires Polansky to do three things as to each claim and each defendant:

- To allege the "**particular details** of a scheme to submit false claims paired with **reliable indicia that lead to a strong inference that claims were actually submitted**." *United States ex rel. Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 157–58 (3d Cir. 2014) (emphasis added).

- To "support [his] allegations with **all of the essential factual background** that would accompany the first paragraph of any newspaper story—that is, **the who, what, when, where and how of the events at issue**." *United States ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 307 (3d Cir. 2016) (emphasis added) (quotations omitted).
- Rather than offer combined allegations about all defendants, to make allegations as to each defendant with "enough particularity to place defendants **on notice of the precise misconduct with which *they* are charged**." *Petras*, 857 F.3d at 502 (emphasis added); *see also Tredennick v. Bone*, 323 F. App'x 103, 105 (3d Cir. 2008) ("where multiple defendants are involved, the complaint should inform each defendant of the nature of his alleged participation in the fraud").

In reviewing this motion, the Court may take judicial notice of the contents of the docket in another federal case—not for the truth of what the documents there assert, but for the fact of what was pleaded and when. *See Burton v. Nationstar Mortg. LLC*, 255 F. Supp. 3d 616, 619 (E.D. Pa. 2015) (citations omitted) ("[A] court may take judicial notice of a filing in a prior case in ruling on a motion to dismiss, but it can only do so to establish the existence of that filing, not for the truth of the facts asserted therein."); *see e.g.*, *Talley v. Wetzel*, No. 3:18-CV-00868, 2019 WL 4010296, at *1 n. 2 (M.D. Pa. Apr. 22, 2019), *report and recommendation adopted*, No. 3:18CV868, 2019 WL

4013635 n.2 (M.D. Pa. Aug. 23, 2019), *aff'd*, 15 F.4th 275 (3d Cir. 2021); *see also United States ex rel. LaCorte v. SmithKline Beecham Clinical Lab'ys, Inc.*, 149 F.3d 227, 234 (3d Cir. 1998) (in affirming dismissal under the first-to-file bar at the Rule 12(b)(6) stage, the Third Circuit reviewed allegations filed in the earlier case against those in the present case).

V. ARGUMENT

A. Polansky violated the government-action bar.

Section 3730(e)(3) of the False Claims Act—known as the government-action bar—prohibits *qui tam* actions by private relators "based upon allegations or transactions which are the subject of a civil suit or an administrative civil money penalty proceeding in which the Government is already a party." 31 U.S.C. § 3730(e)(3). Every element of this mandatory bar applies here, requiring the Court to dismiss the case.

First, there was a civil suit under the False Claims Act in which the Government was a party: *Polansky I*. The Supreme Court held that the Government became a party in *Polansky I* when it intervened to move to dismiss. *See Polansky*, 599 U.S. at 433. The Court likewise rejected the Government's argument that it could dismiss the case without becoming a party. *Id.* at 430. Accordingly, the Government became a party to *Polansky I* in 2019, prior to when Polansky filed the present action in 2020.

Second, the present case is based on "allegations or transactions which are the subject" of *Polansky I*. The allegation or transaction that is the subject of *Polansky I* is that EHR allegedly caused all of its client-hospitals (expressly including Holy Spirit) to

submit false claims by using EHR's tool to determine inpatient status. Dkt. 428-3 ¶¶ 185-201. The allegation or transaction at issue in *Polansky II* is that three of EHR's client-hospitals allegedly submitted false claims because they used EHR's tool to determine inpatient status. AC ¶ 4. Polansky alleges that "all the Hospital Defendants" here were "standard EHR hospital client[s]" and they acted "[l]ike all EHR client hospitals." AC ¶¶ 19, 135. Thus, *Polansky II* is "based upon" the allegations and transactions in *Polansky I*.

The Third Circuit has not described a specific test for the analysis under § 3730(e)(3), but district courts in this circuit have applied both a test adopted by the Ninth Circuit and a test adopted by the First Circuit. *See, e.g.*, *Sturgeon v. Pharmerica Corp.*, 438 F. Supp. 3d 246, 262 (E.D. Pa. 2020) (citing *United States ex rel. S. Prawer & Co. v. Fleet Bank of Maine*, 24 F.3d 320, 327-28 (1st Cir. 1994) (overruled on other grounds) and *United States ex rel. Kelly v. Boeing Co.*, 9 F.3d 743, 746 (9th Cir. 1993)). Polansky loses under either test.

The Ninth Circuit test turns on whether the second case is "based on the same underlying facts" as the first case. *Sturgeon*, 438 F. Supp. 3d at 262 (citing *Boeing Co.*, 9 F.3d at 746); *see also United States ex rel. Bennett v. Biotronik, Inc.*, 876 F.3d 1011, 1016–19 (9th Cir. 2017). It is "essentially a test of factual similarity." *Sturgeon,* 438 F. Supp 3d at 262. Here, the Defendants request that the Court take judicial notice of the pleadings, briefs, and rulings in *Polansky I*—not for the truth of the facts asserted therein, but for purposes of establishing what allegations the earlier case asserted. Doing so confirms

that *Polansky II* is based upon the same factual allegations and alleged fraudulent scheme as *Polansky I*. The overlap between the two cases is described in detail in § III.E of this brief, above, and that discussion is respectfully incorporated by reference here.

In short, in *Polansky I*, Polansky alleged that EHR's system uses the wrong criteria and causes hospitals to bill patients as inpatients rather than outpatients or under observation status. Dkt. 428-3 ¶ 2. He alleged "a nationwide scheme to defraud Medicare and Medicaid engineered by [EHR] … with approximately 2,400 hospitals in 50 states using its services" (*id.*) and just as here he alleged that EHR conspired with hospitals, including Holy Spirit, to submit false claims based on allegedly improper classification of patients. AC ¶¶ 191–92. In *Polansky I*, Polansky named two hospitals as defendants, and lobbed the same allegations at them as Polansky does at the Hospital Defendants here. *See* Dkt. 428-3. And the allegations as to why EHR's systems allegedly gave rise to falsity are the same between the two actions. Compare Dkt. 428-3 ¶ 119 with AC ¶ 103. *Polansky I* specifically relied on allegations about Polansky's work at Holy Spirit, which it identified by name. Dkt. 428-3 at 275 (noting that the allegations in *Polansky* I are "grounded in information about EHR that Dr. Polansky learned ... at Holy Spirit Health Systems"). The present case simply repeats allegations about the same supposed scheme, which Polansky likewise learned of during his work at Holy Spirit, while asserting that the Hospital Defendants acted "[l]ike all EHR client hospitals." AC ¶¶ 19, 135. Thus, under the Ninth Circuit's test, *Polansky II* is barred.

Similarly, the First Circuit test asks if the second case "receiv[es] 'support, advantage, or the like' from the 'host' case (in which the Government is a party) 'without giving any useful or proper return' to the Government (or at least having the potential to do so)." *Sturgeon*, 438 F. Supp. 3d at 262 (citing *Prawer*, 24 F.3d at 327–38. It asks whether there is a "host/parasite" relationship between the two cases. *Id.* If *Polansky I* is a host, *Polansky II* is a parasite. If the allegations in *Polansky I* were stripped from the complaint here, it would be almost empty save for the caption and signature page. *Polansky II* offers no "useful or proper return" to the Government not found in *Polansky I*. Thus, Polansky also fails the First Circuit test.

This is not curable. It requires dismissal with prejudice. And Polansky has no viable counterarguments. He may attempt to argue that because *Polansky I* is now over, the government-action bar should not apply any longer. This argument holds no water. *See United States ex rel. Est. of Gadbois v. PharMerica Corp.*, 292 F. Supp. 3d 570, 578–79 (D.R.I. 2017) ("had Congress wanted the government action bar to have the same reach as the pending case bar, it likely would have included this word"). The Ninth Circuit carefully analyzed and then rejected this argument in *Biotronik, Inc.*, 876 F.3d at 1016–17, 1021 (finding that, for the purposes of § 3730(e)(3), the government is still a party to lawsuits that have concluded). That court noted that Congress included a requirement that the other case be "pending" (at the time of filing) in the first-to-file bar (§ 3730(b)(5)) but *not* in the government-action bar (§ 3730(e)(3))—and Congress's decision must be honored. *Id.* at 1015. In any event, *Polansky I* was pending when this

case was filed—the complaint was filed on April 10, 2020 and *Polansky I* remained pending until 2023.

Nor can *Polansky II* survive because the statute uses the present tense (i.e., it references a case where the Government "is already a party") and the earlier case is now over. The analysis "hinges not on the definition of the word 'is,' but rather on the definition of the phrase 'is already a party.' Our legal system instructs that a party remains a party even after litigation ends." *Biotronik, Inc.*, 876 F.3d at 1016–17.[6] Furthermore, the Ninth Circuit emphasized that "[s]tatutory context only buttresses this interpretation. Under § 3730(e)(4), which immediately follows § 3730(e)(3), it is clear that the Government remains a 'party' to an action after the action has concluded." *Id.* This is because § 3730(e)(4) bars cases based on prior allegations or transactions that "*were* publicly disclosed" in an earlier case in which the Government "*is* a party." *Id.* (emphasis added).

Or perhaps Polansky may argue that the rule does not apply because he was an original source of the allegations. But controlling precedent from the Third Circuit holds that this does not matter in the context of the government-action bar. *U.S. ex rel. Stinson, Lyons, Gerlin & Bustamante, P.A. v. Prudential Ins. Co.*, 944 F.2d 1149, 1156 (3d Cir. 1991) ("Subsection (e)(3) precludes private plaintiffs from bringing suits based on

[6] *Biotronik* notes that a party can file a Rule 60(b) motion after final judgment and the case is closed. *Id.* at 1017. Yet there is no question that the movant would be a "party" in that circumstance, even though the case is over. *Id.*

information or allegations that are the subject of a suit in which the Government is a party … even if the private plaintiff was the original source of the information.").

Thus, the government-action bar requires the Court to dismiss this case. Because this problem cannot be cured, the Court should dismiss with prejudice and without leave to amend. And because this outcome would completely resolve the matter, if it does so the Court need go no further in addressing the remaining grounds for this motion to dismiss.

B. Polansky violated the first-to-file bar.

Section 3730(b)(5) of the False Claims Act—known as the first-to-file bar—prohibits "claims arising from events that are already the subject of existing suits." *United States ex rel. LaCorte v. SmithKline Beecham Clinical Lab'ys, Inc.*, 149 F.3d 227, 232 (3d Cir. 1998); *see* 31 U.S.C. § 3730(b)(5) ("When a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action.").

This case violates the first-to-file bar. ***First***, Polansky filed it on April 10, 2020, at which time *Polansky I* was pending before the Third Circuit. *See Polansky v. Exec. Health Res. Inc*, 17 F.4th 376, 382 (3d Cir. 2021). *Polansky I* remained unresolved until 2023. *United States, ex rel. Polansky v. Exec. Health Res., Inc.*, 599 U.S. 419 (2023). Courts that have considered the question have held consistently that "pending" includes cases pending on appeal. *See, e.g.*, *Carrera v. First Am. Home Buyers Prot. Co.*, No. CV1110242GHKFFMX, 2012 WL 13012698, at *3 (C.D. Cal. Jan. 24, 2012) ("the first-

to-file is applicable even when the first-filed case is pending on appeal."). The Supreme Court's analysis in *Kellogg Brown & Root Servs., Inc. v. U.S., ex rel. Carter*, 575 U.S. 650 (2015) is consistent: it noted that "the District Court dismissed this second complaint under the first-to-file rule because respondent's own earlier case was still pending on appeal" and then held that "the term 'pending' means 'remaining undecided; awaiting decision'" and "[w]e see no reason not to interpret the term "pending" in the [False Claims Act] in accordance with its ordinary meaning." *Id.* at 655, 662 (citations omitted). And in contexts outside the False Claims Act, courts hold that "pending" includes cases pending on appeal. *Eikenberry v. Callahan*, 653 F.2d 632, 635 (D.C. Cir. 1981) ("The ordinary meaning of 'pending' includes cases pending on appeal"); *Burger v. Am. Maritimes Officers Union*, No. 97–31099, 1999 WL 46962, at *1 (5th Cir. Jan. 27, 1999) ("the same policy concerns for avoiding duplicative litigation and comity exist when a similar matter is pending in a federal district court and a federal court of appeals in a different circuit." (internal citations omitted)). The docket in *Polansky I* was not closed until September 2023. *See* Case No. 2:12-cv-04239-MMB.

Second, for reasons set out in §§ III.E and V.A, above, which are respectfully incorporated by reference here, *Polansky II* is "based on the facts underlying" *Polansky I*. Under Third Circuit law,

> A later case need not rest on precisely the same facts as a previous claim to run afoul of this statutory bar. Rather, if a later allegation states all the essential facts of a previously-filed claim, the two are related and section 3730(b)(5) bars the later claim, even if that claim incorporates somewhat different details.

LaCorte, 149 F.3d at 232–33. *LaCorte* is controlling here: the cases both turn on the same essential allegations about EHR causing hospitals to submit false claims, and the bar applies even if *Polansky II* arguably includes some new or different details.

Thus, the first-to-file bar requires dismissal of this case. *See LaCorte*, 149 F.3d 227 at 238 (affirming dismissal due to application of the first-to-file bar); *Hallstrom v. Tillamook Cnty.*, 493 U.S. 20, 31 (1989) ("As a general rule, if an action is barred by the terms of a statute, it must be dismissed."). As three circuit courts of appeal have held, an amended complaint does not cure the first-to-file problem—only a filing a new case could do so. This was the conclusion of the D.C. Circuit in 2017. *See United States ex rel. Shea v. Cellco P'ship*, 863 F.3d 923, 929 (D.C. Cir. 2017) ("A supplemental or amended complaint, however, could not remedy [relator's] violation of the first-to-file bar. [Relator] infringed the first-to-file bar by bringing a related action while his first-filed case remained pending. Although [Relator's] first-filed suit is no longer pending, a supplemental complaint cannot change when [Relator] brought his second action for purposes of the statutory bar."). [7] The Second Circuit reached the same conclusion in 2018. *United States ex rel. Wood v. Allergan, Inc.*, 899 F.3d 163, 170 (2d Cir. 2018) (holding that relator's "position that a violation of the first-to-file bar can be cured by the filing of an amended pleading is inconsistent with the language of the statute."). And the

[7] The Third Circuit has not addressed this issue directly, but has cited other aspects of *Shea* with approval. *See United States v. Omnicare, Inc.*, 903 F.3d 78, 89 (3d Cir. 2018).

Fourth Circuit reached the same answer in 2017. *United States ex rel. Carter v. Halliburton Co.*, 866 F.3d 199 (4th Cir. 2017).

The core of these holdings is the plain language of the statute: the statute prohibits bringing an *action* while another case is pending, and the remedy for doing so is dismissal of the *action*. An amended complaint does not change when the action was brought, or erase the violation that occurred when it was. *Shea*, 863 F.3d at 929. As *Halliburton* explains, the False Claims Act "imposes a restriction on the 'bring[ing]' of an 'action'" while another is pending, and "[i]n ordinary parlance, one "bring[s] an action" by "institut[ing] legal proceedings." 866 F.3d at 206 (citing 31 U.S.C. § 3730(b)(5) and *Bring an Action*, Black's Law Dictionary 231 (10th ed. 2014)). *Halliburton* also referenced the Supreme Court's holding in another recent case where "the Court contrasted the seal requirement with the first-to-file rule, which the Court described as one of 'a number of [FCA] provisions that do require, in express terms, the dismissal of a relator's action.'" *Id.* at 208-09 (citing *State Farm Fire & Cas. Co. v. United States ex rel. Rigsby*, 137 S. Ct. 436, 440, 196 L.Ed.2d 340 (2016)). "This reasoning by the Supreme Court confirms that the only appropriate response for a first-to-file rule violation is dismissal." *Id.* Similarly, as the Supreme Court held earlier in *Hallstrom,* the "general rule" is that "if an action is barred by the terms of a statute, it must be dismissed." 493 U.S. at 31. The Second Circuit's opinion follows a similar analysis, and adds another point: if an amended complaint relates back for the purpose of the statute of limitations, then it must relate back for the purposes for the first-to-file rule—and to suggest

otherwise is internally inconsistent. *Allergan.*, 899 F.3d at 172 n.7. Thus, this *action* must be dismissed.

C. Collateral estoppel bars Polansky's EHR theory.

In *Polansky I*, Polansky alleged that EHR caused each of its hospital clients to submit false claims because they took EHR's algorithms and case-review criteria into account when determining whether to bill patients as inpatients, outpatients, or under observation status. *See, e.g.*, Dkt. 428-3 at ¶¶ 2, 89. His pleadings expressly referenced Holy Spirit by name. *Id.* ¶ 277, n.19. These claims were dismissed with prejudice as to Polansky. Dkt. 562. The present case involves the same theory: that the Defendant Hospitals "conspired with their billing vendor, EHR" (AC ¶ 192) to submit claims that were false in the same exact same way alleged in *Polansky I*.

Polansky is collaterally estopped from pursing the same claim here. In the Third Circuit,

> [i]ssue preclusion, or collateral estoppel, prevents parties from relitigating an issue that has already been actually litigated. The prerequisites for the application of issue preclusion are satisfied when: (1) the issue sought to be precluded is the same as that involved in the prior action; (2) that issue was actually litigated; (3) it was determined by a final and valid judgment; and (4) the determination was essential to the prior judgment.

Peloro v. United States, 488 F.3d 163, 174–75 (3d Cir. 2007) (citations and alterations omitted). That the Defendants were not parties in *Polansky I* is no barrier. "Under the modern doctrine of non-mutual issue preclusion ... a litigant may also be estopped from advancing a position that he or she has presented and lost in a prior proceeding against

a different adversary." *Id.* (citing *Blonder–Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 324 (1971). For defensive collateral estoppel—a form of non-mutual issue preclusion—to apply, the party to be precluded must have had a "full and fair" opportunity to litigate the issue in the first action. *Id.* All of these prerequisites are met here:

First, the issue to be precluded is the same. Section III.E of this brief lays out in detail the overlap between the complaints in *Polansky I* and *Polansky II,* and explains that the same EHR theory is at the core of both cases; that discussion is respectfully incorporated by reference here.

As to the ***second*** and ***fourth*** prongs, the issue (Polansky's theory that EHR's approach violates the False Claims Act) was litigated in *Polansky I*, and its determination was essential to the final judgment. Polansky filed three complaints in *Polansky I*; EHR and the hospital defendants in that case filed several motions to dismiss; the parties briefed and the court ruled on summary judgment. Dkt. 561. Both the Government's motion to dismiss and the court's ruling on that motion extensively analyzed the merits of the case. For example, the Government's opening brief emphasized that its motion to dismiss was based on "developments in the case, including arguments raised by the parties [and] further factual and evidentiary developments…." Dkt. 526 at 2 (quotations omitted). And the Government's reply discussed "its significant concerns regarding shortcoming in the evidence amassed by Relator, including Relator's deposition testimony." Dkt. 554 at 5. The Government "ha[d] substantial concerns about the

Relator's ability to prevail in this case" and those concerns were part of the Government's reasoning and showing of "good cause" to dismiss. *Id.* at 6.

The district court's 2014 ruling granting the hospitals' motion to dismiss and its 2019 ruling granting the Government's motion to dismiss both analyzed the merits of the EHR theory. The 2019 ruling noted that the court expressly requested a supplemental brief from the Government on the merits of the EHR theory. Dkt. 561 at 7. That ruling includes a merits analysis as additional support for dismissal. *Id.* at § III.B. Critically, the court expressly cited the Government's "genuine concerns" about the merits as a basis to find that the Government had proven good cause to dismiss the case. *Id.* at 16.

The Supreme Court echoed this point that an assessment of the merits was part of the grounds for dismissal in *Polansky I*: "the Government explained in detail why it had come to believe that the suit had little chance of success on the merits. Polansky vigorously disputed the latter point, claiming that the Government was "leaving billions of dollars of potential recovery on the table." *Polansky,* 599 U.S. at 438.

While case law on § 3730(c)(2)(A) dismissals is limited, a case from the United States District Court for the Eastern District of Illinois confirmed that such a dismissal is a preclusive merits determination. *See Illinois ex rel. Strakusek v. Omnicare, Inc.*, No. 19 C 7247, 2021 WL 308887, at *5–6 (N.D. Ill. Jan. 29, 2021). In the context of claim preclusion, it held that a § 3730(c)(2)(A) dismissal "with prejudice as to the Relator" has preclusive effect, even where the dismissing court *did not* delve into the merits of the

relator's case. *Id.* at *6. Here, the case for preclusion is even stronger, where the *Polansky I* court clearly evaluated the merits of Polansky's claim.

Finally, on the ***third*** prong, there is no question that the ruling in *Polansky I* was a valid and final judgment. Indeed, the Supreme Court directly "affirm[ed] in all respects the judgment below." 599 U.S. at 439.

Accordingly, Polansky's EHR theory is barred by collateral estoppel, and the present complaint should be dismissed with prejudice. To be sure, we do not contend that collateral estoppel would bar the Government from pursuing these claims. The dismissal in *Polansky I* was without prejudice to the United States, and with prejudice only to Polansky. This distinction must mean something. As to Polansky, it means that this case should be dismissed.

D. Polansky has not pleaded any violations within the statute of limitations.

1. Claims for violations before April 10, 2014 are outside the statute of limitations.

The statute of limitations for a False Claims Act case is set out in 31 U.S.C § 3731(b). *See Cochise Consultancy, Inc. v. United States ex rel. Hunt*, 139 S. Ct. 1507, 1510 (2019). Such a case may not be filed:

> (1) more than 6 years after the date on which [the violation] is committed, or
>
> (2) more than 3 years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances ...

whichever occurs last.

31 U.S.C. § 3731(b).

The application of subsection (1) is straightforward. Polansky filed the original complaint under seal on April 10, 2020. *See* Dkt. 1. Thus, claims before April 10, 2014 (six years prior) are barred.

Subsection (2) does not extend that deadline here because under the facts of this case, it would offer an earlier cut-off date. Polansky filed his first complaint in *Polansky I* on July 26, 2012. The False Claims Act requires that at the time of filing a *qui tam*, "copy of the complaint and written disclosure of substantially all material evidence and information the person possesses shall be served on the Government." 31 U.S.C. § 3730(b)(2). The law requires that the Government "diligently … investigate" this information. *Id.* at § 3730(a). Later, the Government required the parties to serve all pleadings and orders on it throughout the case. *See* Dkt. 19. And of course, the Government actively participated throughout the case, including by filing a motion to dismiss. *See* Dkt. 526. Accordingly, the Government (through the Department of Justice, which has responsibility for filing False Claims Act suits, *see Hunt*, 139 S. Ct. at 1510) was on notice of "facts material to the right of action" no later than 2012. Because the three-year period under § 3731(b)(2) would not extend the deadline in this case, the six-year period in (b)(1) controls, and claims before April 10, 2014 are barred.

Polansky appears to concede this point. His amended complaint now limits his claims and the scope of the alleged violations by replacing earlier references to 2010

with references to 2014. *See e.g.*, OC ¶ 2 and AC ¶ 2; OC ¶ 89 and AC ¶ 88; OC ¶ 186 and AC ¶ 184; OC ¶ 187 and AC ¶ 185 (each replacing "2010" with "2014").

2. Polansky has not pleaded any facts to suggest that false claims were submitted on or after April 10, 2014.

Polansky's role at Holy Spirit ended in May 2014. AC ¶ 31. He notes that Holy Spirit was sold and became part of a new health system, Geisinger Health, *after* he left. *Id.* at ¶ 32. He acknowledges that his "first-hand" knowledge ended when he left the hospital. AC ¶ 60. The best he can offer is a negative inference, that he is "unaware that any of the Hospital Defendants changed their practices" after he left. AC ¶ 149.

It is thus no surprise that a close reading of his complaint reveals that it contains essentially no allegations about events that occurred inside the statute-of-limitations period, or during the period when each hospital was part of Geisinger Health. The latest allegation is that a government vendor denied some of Holy Spirit's appeals in a decision on April 2, 2014 (*see* AC ¶ 135) involving claims submitted earlier—outside the limitations period. And every one of the example cases and patients described in *Exhibits A*, *B*, *C*, and *D* to the complaint is from before April 10, 2014.

In short, Polansky has offered no "reliable indicia that lead to a strong inference that claims were actually submitted," *see Foglia*, 754 F.3d at 155, within the statute of limitations. He is required to do so, to avoid dismissal. *See Int'l Strategic Cancer All., LLC v. Stichting Katholieke Universiteit*, No. CV 17-2024, 2017 WL 4681789, at *3 (E.D. Pa. Oct. 18, 2017) ("Plaintiff must allege sufficient facts to bring the fraud claim within the

two year statute of limitations."); *see also United States ex rel. Brooks v. Trillium Cmty. Health Plan, Inc.*, No. 6:14-CV-1424-MC, 2017 WL 2805863, at *2 (D. Or. June 28, 2017) (dismissing False Claims Act case because relator failed to plead violations within statute of limitations with sufficient particularity); *Manosca v. Wachovia Mortg.*, No. C 11-2183 SI, 2011 WL 2970824, at *5 (N.D. Cal. July 20, 2011) ("[P]laintiff must plead the fraud claim with particularity as required by Federal Rule of Civil Procedure 9(b) [and] the claim must be based on events that fall within the … statute of limitations."); *United States ex rel. Foster v. Bristol-Myers Squibb Co.*, 587 F. Supp. 2d 805, 827 (E.D. Tex. 2008) (dismissing counts in False Claims Act case after finding that certain claims were outside limitations period, and relator had not satisfied Rule 9(b) as to claims inside limitations period). The best Polansky can offer is a weak inference on the grounds that "[t]here was no indication" to him "at the time of his termination" that the practices involving EHR would change. AC ¶ 152. This is not the "reliable indicia" required. *See Foglia,* 754 F.3d at 155. Thus, the amended complaint should be dismissed under the statute of limitations.

E. The Stark Act count fails under Rules 12(b)(6) and 9(b).

In his amended complaint, Polansky asserts for the first time that two defendants—Holy Spirit and Spirit Physician Services—violated the Stark Act, 42 U.S.C. § 1395nn(b)(4). This claim and theory were not part of the case that Polansky presented to the Government under seal (as the False Claims Act requires) and the Government did not have an opportunity to investigate it. Instead, Polansky added this

claim four years after the case was filed. This alone is grounds to dismiss the claim. *See United States v. Walgreen Co.*, No. CV09-1293 PSG PJWX, 2017 WL 10591756, at *4 (C.D. Cal. May 1, 2017) (denying leave to amend *qui tam* complaint to add new claim that was not substantially similar to the claims presented to the government). But there are several additional reasons the Court should dismiss Polansky's Stark Act claim as well.

Polansky's new Stark Act theory is this: one component of the compensation that Spirit Physician Services paid to its employed doctors (known as hospitalists) was a bonus program calculated based on the units of work, called relative value units or "RVUs," that they performed at the hospital. AC ¶¶ 168-170. The number of RVUs for each kind of patient encounter are not set by Geisinger, but rather by the Government. *See* 42 C.F.R. § 414.22 ("CMS establishes RVUs for physicians' work…."); *see also Ball v. Einstein Cmty. Health Assocs., Inc.*, 514 F. App'x 196, 198 n.1 (3d Cir. 2013) (RVUs "attempt to account for the work performed by a physician, the physician's training and expertise, the type of equipment used and the professional liability insurance required" and are a "standardized system" used by "[p]rivate health insurers, Medicare, and Medicaid"). According to Polansky, when a hospitalist treats a patient, the "number of units of work for a case is greater if a patient is in inpatient status than if the patient is in outpatient status." AC ¶ 170.

To be clear, Polansky *does not* allege that hospitalists are paid extra to admit inpatients (i.e., $100 per admission, or the like). He *does not* allege that more RVUs are

awarded for the admission decision itself. Rather, the supposed incentive is that the hospitalists' bonuses are higher when there are proportionately more inpatients in the hospital to treat, because treating someone who is an inpatient results in more RVUs. As Polansky sees things, doctors should be paid the same when treating inpatients and observation-status patients (regardless of whether the former have serious conditions justifying inpatient status). Here again, Polansky's personal views depart from both the law and from common practice across the healthcare industry.

1. The claim against Spirit Physician Services fails.

The Stark Act "forbids submitting Medicare claims for 'designated health services' provided under a 'referral' made by a doctor with whom the [billing] entity has a 'financial relationship'" unless an exception applies. *United States ex rel. Bookwalter v. UPMC*, 946 F.3d 162, 168 (3d Cir. 2019) (citing 42 U.S.C. § 1395nn). Like the relator in *Bookwalter*, Polansky's theory is about a "financial relationship" involving a "compensation arrangement." *Id.* As the Third Circuit emphasized, these quoted terms have highly technical meanings. *See id.*

The claim against Spirit Physician Services fails as a matter of law for two straightforward reasons. ***First,*** while inpatient hospital services (which Holy Spirit provides and bills for) are "designated health services," a doctor's professional services associated with the hospital care (which the doctors provide, and which Spirit Physician Services bills for) are *not* "designated health services." "'Inpatient hospital services' do not include professional services performed by physicians…." 42 C.F.R. § 411.351.

Thus, the hospitalists do not refer "designated health services" to Spirit Physician Services, and a required element of any Stark Act claim is missing as to this defendant.

Second, as a matter of law, there is no "referral" as to Spirit Physician Services at all, even if the professional services did count as designated health services (which they do not). 42 C.F.R. § 411.351, which defines "referral," states that a referral *does not include* "any designated health service personally performed or provided by the referring physician." 42 C.F.R. § 411.351. What Spirit Physician Services bills for are professional fees for the services performed by the hospitalists. AC ¶ 170 (referencing the "professional claims submitted by Spirit Physicians Services" to the Government). Because these are personally provided services (i.e., they are performed personally by the hospitalists), there is no "referral" under the Stark Act. This is another required element of the claim that is missing here—and a second independent basis that requires dismissal of the Stark Act claim against Spirit Physician Services.

2. The claim against Holy Spirit fails.

The heart of Polansky's new Stark Act claim is an "indirect compensation" theory against Holy Spirit. *See* AC ¶¶ 196, 197 (asserting an indirect compensation arrangement).[8] But this theory too fails as a matter of law.

Over the last ten years, CMS has strongly rejected Polansky's simplistic conclusion that all compensation based on RVUs violates the Stark Act. Compensation

[8] It is "indirect" as to Holy Spirit because the hospitalists work for and are paid by Spirit Physician Services.

based on RVUs (i.e., relative value units) is known as unit-based compensation. *Bookwalter*, 946 F.3d at 171. In 2021, CMS confirmed that such compensation implicates the Stark Act "only if the formula used to calculate the physician's … compensation includes the physician's referrals to the entity **as a variable**." 42 C.F.R. § 411.354(d)(5)(i) (emphasis added). CMS made this clarification because of the importance and prevalence of unit-based compensation. As the preamble text states, "[a]ll of the commenters noted that productivity pay for personally performed services is among the most prevalent compensation methodologies used by hospitals…." Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations, 85 Fed. Reg. 77492-01 (Dec. 2, 2020). The Government itself uses a similar approach to determine the compensation paid as professional fees for doctors who bill the Government directly for their services (as opposed to working as employees of a group like Spirit Physician Services, which in turn bills the Government).[9]

Polansky's theory asserts that all of this RVU-based compensation is illegal because it takes into account the volume or value of the physician's referrals to the hospital. He is wrong. Certainly, as to the compensation discussed in the complaint, he has not alleged that referrals are a "variable" in the hospitalists compensation formula. His theory is far more attenuated: more admissions means more inpatients, and more

[9] Doctors who bill the government directly are paid under the Medicare Physician Fee Schedule, which is based in part on RVUs. *See* 42 U.S.C. § 1395w-4; 42 C.F.R. § 414.20.

inpatients to care for results in more opportunities to earn RVUs. Because he has not alleged facts to show that the doctors are paid per referral, his claim fails as a matter of law.

Even before § 411.354(d)(5)(i), the same conclusion still holds. CMS has explained that "[t]o be clear," prior to § 411.354(d)(5)(i), unit-based compensation was nonetheless permissible under § 411.354(d)(2). 85 FR 77492-01 ("these policies would be applied when analyzing compensation arrangements for compliance with the physician self-referral law during periods prior to the effective date of this final rule."). Section 411.354(d)(2) states that:

> Unit-based compensation (including time-based or per-unit of service-based compensation) is deemed not to take into account the volume or value of referrals if the compensation is fair market value for items or services actually provided and does not vary during the course of the compensation arrangement in any manner that takes into account referrals of designated health services.

Id. **CMS has emphasized that there is a critical but subtle distinction in this language:** "[w]e note that the special rules use the phrase 'takes into account referrals' (or other business generated) rather than 'takes into account the volume or value of referrals' (or other business generated)." 85 FR 77492-01. This means that the RVU formula to which Polansky objects does not violate (d)(2). Even if it somehow accounts for the *value* of referrals in an attenuated way, Polansky does not allege that it actually takes into account referrals (i.e., $100 per referral, or the like). Thus, there is no Stark Act violation.

The same conclusion follows from Third Circuit precedent that predates CMS's clarifications. "Under the Stark Act and its regulations, compensation takes into account referrals if there is a causal relationship between the two." *Bookwalter*, 946 F.3d at 171. The core of the Third Circuit's opinion in *Bookwalter* is about determining what allegations are required to meet this standard as to RVU-based compensation. And under this precedent, that turns on whether the compensation paid exceeds fair-market value. *Id.* at 171-72 (citing 69 Fed. Reg. 16054-01 ("unit-of-service, or other 'per click' based arrangements are generally permitted if they are at fair market value without reference to referrals")).

Despite his obligation under Rule 9(b),[10] Polansky fails to plead any facts or details whatsoever to plausibly suggest that the compensation arrangement in question exceeds fair market value. In contrast, the court in *Bookwalter* allowed the RVU-based claim to go forward to discovery because:

> the relators here plead five facts that, viewed together, make plausible claims that the surgeons' pay far exceeded their fair market value. First, some surgeons' pay exceeded their collections. Second, many surgeons' pay exceeded the 90th percentile of neurosurgeons nationwide. Third, many generated Work Units far above industry norms. Fourth, the surgeons' bonus per Work Unit exceeded what the defendants collected on most of those Work Units. And finally, the government alleged in its settlement agreement that the Medical Center had fraudulently inflated the surgeons' Work Units. That much smoke makes fire plausible.

[10] Rule 9(b) applies here, because Polansky's claim is for a violation of the False Claims Act predicated on a Stark Act violation. *Bookwalter*, 946 F.3d at 168.

Bookwalter, 946 F.3d at 172. Polansky's claim fails because he has not pleaded any facts suggesting any of the five "red flag[s]" outlined in *Bookwalter*, or any others. *See* 946 F.3d at 172. He does not allege that compensation exceeded fair-market value. He does not allege that pay exceeded collections. He does not allege that hospitalists' compensation was above the 90th percentile. He does not allege anything with regard to RVUs in excess of industry norms. He does not allege that any bonus exceeded the hospital's collections. And he does not allege that Holy Spirit settled with the Government on the same issue—because that didn't happen here.

The import of *Bookwalter's* discussion about red flags is clear: not all RVU-based compensation arrangements violate the Stark Act. If RVU-based arrangements were deemed to always take into account referrals as Polansky suggests, the discussion about red flags in *Bookwalter* would be moot. Simply pleading an RVU-based compensation arrangement would be enough—and the United States healthcare system would be turned upside down.

The procedural history of *Bookwalter* further confirms this point. The Third Circuit's initial (and now vacated) ruling cast a broad net under which a Stark Act claim based on almost any RVU-based arrangement would survive a motion to dismiss. In response, the defendants—with support from *amici*—successfully sought rehearing. They emphasized that CMS has stated that "all physicians, whether employees, independent contractors, or academic medical center physicians, can be paid productivity bonuses based on work they personally perform." 69 Fed. Reg. 16054,

16067 (Mar. 26, 2004). This is important, because the model to which Polansky objects is commonplace. As *amicus* noted in support of rehearing in *Bookwalter*, in the American Medical Group Association's 2017 survey, 83% of respondents reported the use of wRVUs as a determinant of compensation.[11] In response to these points, the Third Circuit vacated and substantially narrowed its holding—emphasizing that a relator must do *more* than plead the existence of RVU-based bonus compensation to survive a motion to dismiss. The subsequent clarifications from CMS show the same point. But here, Polansky seeks to revert to the now-vacated position that all of these common arrangements violate the Stark Act. The Court should reject this and dismiss the Stark Act claim.

3. Polansky pleaded no details showing a Stark Act violation within the statute of limitations

One of the things that Rule 9(b) requires is details about *when* the alleged violation happened. *Id.* at 176. But here, Polansky has pleaded no details about when claims were submitted allegedly in violation of the Stark Act.

This failure is critical because of the statute of limitations. For the reasons set out in section V.D.1, claims based on alleged compensation arrangements before April 10, 2014 are outside the statute of limitations. To support his Stark Act claim, Polansky alleges that his supposed "compliance efforts" led to fewer inpatient admissions, and

[11] Wayne M. Hartley et al., *Value-Based Care's Impact on Physician Compensation: Pay Increases in Primary Care Amid Stalling Productivity Levels Across Specialties*, Group Practice Journal at 13–14 (Sept. 2017), https://perma.cc/E32G-AN2X.

that the hospitalists made less money as a result. AC ¶ 169. Polansky left Holy Spirit in May 2014 (AC ¶ 90), and so his "compliance efforts," and the effects he observed, must have happened before that. Thus, even if his observation meant that claims were submitted earlier in violation of the Stark Act (and this is not so, for the reasons above), he has pleaded no facts or details whatsoever to suggest a single Stark Act violation inside the statute of limitations. This is another independent basis to dismiss this claim.

F. The False Claims Act counts fail under Rules 12(b)(6) and 9(b).

1. No falsity

To survive dismissal, Polansky must sufficiently allege the submission of a *false* claim, the "*sine qua non*" of any FCA violation. *See The U.S. Dep't Of Transportation, ex rel. Arnold v. CMC Eng'g*, 564 F.3d 673, 676 (3d Cir. 2009). "There are two categories of false claims under the FCA: a factually false claim and a legally false claim." *U.S. ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 305 (3d Cir. 2011). Factually false means a claim that "misrepresents what goods or services that it provided to the Government" and "a claim is legally false when the claimant knowingly falsely certifies that it has complied with a statute or regulation the compliance with which is a condition for Government payment." *Id.*

This case is not about factual falsity. Polansky does not allege that the Defendants misrepresented what goods or services they provided to patients—i.e., he does not claim that the Defendants did not treat the patients they billed for treating.

Cf., AC ¶¶ 73–74 (alleging "hospital status designation does not impact the scope or intensity of services ordered by a treating physician").

Instead, Polansky's theory is about alleged legal falsity. Polansky must therefore sufficiently allege that the Defendants violated a "statutory, regulatory, or contractual requirement," falsely certified their compliance with such "legal requirement," and that this certification was "material to the Government's payment decision." *Escobar*, 136 S. Ct. at 1995–96; *see, e.g.*, *United States ex rel. Whatley v. Eastwick College*, 657 Fed App'x 89, 94 (3d Cir. 2016). In doing so, he must comply with Rule 9(b) by alleging "the "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted" and offering "enough particularly" to place *each defendant* on notice of "the precise misconduct with which they are charged." *Foglia, LLC*, 754 F.3d at 155; *Petras*, 857 F.3d at 502.

Polansky has not pleaded facts sufficient to show falsity, either before or after the Two-Midnight Rule.

a) Claims before the Two-Midnight Rule (before October 2013)[12]

Polansky's theory is that EHR's recommendations are false because they turn on an assessment of how sick a patient is and the patient's likelihood of having an adverse

[12] For the reasons set out in section V.D.1, these claims are outside the statute of limitations, which Polansky appears no longer to contest. However, because the amended complaint still discusses these facts and theories, we address them here.

event—and not exclusively based on an estimate of how long the patient will need to be in the hospital. *See* AC ¶ 5.

On its face, of course, the "reasonable and necessary" rule says nothing about which factors a hospital can consider or which patients should be billed as inpatients, especially where Polansky alleges they receive the same care whether as inpatients or under observation status. *Cf.*, AC ¶¶ 73–74. Thus, Polansky must turn to other standards to try to show falsity. Without more, the complaint references "Manuals" from Polansky's previous employer, CMS. *See* AC ¶¶ 98-100. These Manuals, he asserts, require "an expectation of at least 24 hours of medically necessary hospital services to meet inpatient status…." AC ¶ 100. Thus, he asserts, at least some claims relying on EHR's methodology are false. This fails as a matter of law for two reasons:

***First,* the Manuals on which Polansky relies do not create a controlling standard sufficient to show falsity.** The Medicare Act requires that CMS provide the public with advance notice and an opportunity to comment before adopting a "rule, requirement, or other statement of policy … that establishes or changes a *substantive legal standard*." 42 U.S.C. § 1395hh(a)(2) (emphasis added). CMS did not follow these procedures for the Manual provisions on which Polansky relies. Accordingly, as the district court ruled in *Polansky I*, until October 2013 there were no binding statutes or regulations establishing criteria for coverage and payment of inpatient hospital admissions such that the claims could be objectively true or false. *See Polansky I,* Dkt

561[13]; *see, e.g.*, *In the Case of AHS Hosp. Corp.,* 2013 WL 8719878, at *1 (HHS Aug. 30, 2013) ("There are no binding statutes, regulations, or NCDs which establish criteria for coverage and payment of inpatient hospital admissions."). But under *Allina* and *Escobar*, Polansky cannot transform non-binding guidance into substantive legal standards that can form the basis of falsity and false-claims liability.

In *Allina,* the Supreme Court concluded that a "substantive legal standard" triggering notice-and-comment rulemaking under the Medicare Act is unique. 139 S.Ct at 1814. As a result of this distinction, *Allina* left open that interpretive rules, such as "'gap'-filling polic[ies]" like the Manuals in question here, could trigger the notice-and-comment requirement if they establish or change a substantive legal standard. *Id.* at 1811–17; *see also Polansky I*, Dkt. 561 at 26–27 (citing *Select Specialty Hosp.-Denver, Inc. v. Azar*, 391 F. Supp. 3d 53, 67 (D.D.C. 2019)); *Yale New Haven Hosp. v. Azar*, No. 18-1230, 2019 WL 3387041, at *7 (D. Conn. July 25, 2019)).

Because the Supreme Court in *Allina* did not provide a bright-line definition of "substantive legal standard," the Court in *Polansky I* adopted the District of Columbia Circuit's formulation, which defined it to "at a minimum include[] a standard that creates, defines, and regulates the rights, duties, and powers of parties." Dkt. 561 at 27–

[13] Because the district court first granted the motion to dismiss, the Third Circuit found that it did not need to reach the district court's summary judgment decision and ultimately vacated the district court's opinion and order as to summary judgment. *Polansky*, 17 F.4th at 382 n.4.

28 (quoting *Allina Health Servs. v. Price*, 863 F.3d 937, 943 (D.C. Cir. 2017)). That is precisely how Polansky proposes to use the Manuals' standards: to prove that EHR's formula is false or contrary to law. Applying this definition, the court found that the 24-hour policy expressed only in CMS Manuals prior to the implementation of the Two-Midnight Rule "set[] the standard by which a hospital's entitlement to the higher reimbursement rate for inpatient claims is assessed" and is therefore a "substantive legal standard" under the Medicare Act. Dkt. 561 at 29–30. (citing *Allina*, 139 S. Ct. at 1811).

The Manuals which Polansky relies on never underwent notice-and-comment rulemaking and were only conveyed through this non-binding manual guidance. Dkt 561 at 25. Polansky relies directly on these provisions to try to show that the Defendants submitted false claims. Accordingly, he invokes them to set the legal standard, and to show why the Defendants' claims are legally false. But without notice-and-comment rulemaking, the Manuals cannot play this role.

***Second,* even if they were binding, Polansky has not pleaded facts to show a violation of the standard in the Manuals.** He does not cite or describe a rule that the Hospital Defendants allegedly violated during this period. Because the Manuals are government documents that are referenced in the complaint, they are subject to judicial notice.[14] The operative version of the Manual explains that "the decision to admit a

[14] Polansky attached excerpts of these manuals to his opposition to EHR's Motion to Dismiss in *Polansky I*. Dkt. 442. They are attached again here for the Court's reference. The Defendants respectfully request that the Court take judicial notice of these as reliable government documents "whose accuracy cannot be reasonably be

patient is a *complex medical judgment* which can be made only after the physician has considered a number of factors, including the patient's medical history and current medical needs…." Dkt. 442-4 at 2 (emphasis added). The Manual goes on to explain that the decision is multifactored and factors to be considered include:

- "[t]he severity of the signs and symptoms exhibited by the patient,"
- "[t]he medical predictability of something adverse happening to the patient,"
- "[t]he need for diagnostic studies that appropriately are outpatient services (i.e., their performance does not ordinarily require the patient to remain at the hospital for 24 hours or more) to assist in assessing whether the patient should be admitted" and
- "[t]he availability of diagnostic procedures at the time when and at the location where the patient presents."

Id. at 2.

Polansky has not pleaded facts that show a violation of these standards. He asserts that EHR's tools are improper because they take into account acuity rather than duration, but these are two sides of the same coin. Indeed, the regulations themselves

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questioned." Fed. R. Civ. P. 201(b)(2); *see Kos Pharma., Inc. v. Andrx Corp.*, 369 F.3d 700, 705 n.5 (3d Cir.2004). Furthermore, the Court may also rely on them as incorporated by reference in the complaint. AC ¶¶ 98, 101, 158; *see In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) ("[A] document integral to or explicitly relied upon in the complaint may be considered without converting the motion to dismiss into one for summary judgment.") (cleaned up).

confirm that it is appropriate to consider the chance of an adverse event, need for diagnostic studies, and "severity" of the patient's symptoms. *Id.* Under the Government's own rules, these are inputs that help determine expected duration and thus inpatient status. Yet Polansky asserts the Hospital Defendants' claims are false for taking these factors into account. AC ¶ 5.

Polansky calls EHR's approach "fake science" or "junk science," but does not plead facts to show why that is. Conclusions and labels are not enough. *Twombly*, 550 U.S. at 555. While it appears that Polansky disagrees with EHR's methodology, he has not pleaded any facts to suggest why its methods are "fake" but other screening products like McKesson's InterQual (*see* AC ¶ 61) are not "fake." Simply using a label—calling EHR's review criteria fake science—is exactly what *Twombly* prohibits. Thus, under the rigorous standards of Rule 9(b), Polansky has failed to plead facts that lead to a strong inference of falsity.

b) Claims under the Two-Midnight Rule (after October 2013)

It is telling that Polansky does not actually quote the Two-Midnight Rule—that is, the regulatory provision that addresses the central issue in the case—anywhere in his 100-page amended complaint.

Here is what the Two-Midnight Rule says. First, it describes the benchmark: "an inpatient admission is generally appropriate ... when the admitting physician expects the patient to require hospital care that crosses two midnights." 42 C.F.R. § 412.3(d)(1).

However, "[t]he expectation of the physician should be based on such complex medical factors as patient history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event." *Id.* The rule notes that the inpatient admission remains appropriate where "unforeseen circumstances" mean the patient ends up spending less time in the hospital. *Id.* Finally, the last section of the rule provides that some patients are appropriate to admit as inpatients even where the physician does not expect the care to exceed two midnights:

> Where the admitting physician expects a patient to require hospital care for only a limited period of time that does not cross 2 midnights, an inpatient admission may be appropriate … based on the clinical judgment of the admitting physician and medical record support for that determination. The physician's decision should be based on such complex medical factors as patient history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event ....

42 C.F.R. § 412.3(d)(3).

Stripped of its rhetoric, the complaint simply has not pleaded facts that show a violation of this rule. Polansky's allegation that EHR's methodology considers account patient acuity and risk of adverse events does not violate the rule, where the rule expressly permits physicians to consider complex medical factors, and risk of an adverse event. He admits that "the simple fact that EHR certified a claim as inpatient does not mean, *per se,* that the proper medical necessity determination would in every case have led to a different result." AC ¶ 73. And his allegation that EHR's criteria suggests different conclusions than those made with InterQual criteria in a "substantial majority" of cases does not give rise to any inference—let alone the strong inference

required by the law—of false claims. *See* AC ¶ 85. After all, InterQual is just a different tool from a different private company, used to evaluate patient risk and help with admissions decisions. *See* AC ¶ 61. Polansky has not pleaded any facts to show that InterQual's answers comply with the rule but EHR's do not—other than asserting his opinion in conclusory terms that the former is "legitimate" but the latter is "fake science." AC ¶¶ 85, 5. These are labels, not facts, and they do not satisfy Rules 8 and 9(b).

c) Polansky does not plead specifics to support his other falsity theories.

While Polansky's allegations about length-of-stay versus risk are the core of his claims, he also offers three backup theories: that the Hospital Defendants violated regulations about the use of Utilization Review ("UR") functions (AC ¶ 104); that they violated regulations requiring that physicians are the ones who issue orders admitting patients to a hospital (AC ¶ 106); and that they violated regulations stating that ordering decisions must reflect medical necessity as of the time they are written (AC ¶ 110). The problem here is that Polansky has not pleaded the "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted" or offered "enough particularly" to place each defendant on notice of "the precise misconduct with which they are charged." *Foglia, LLC*, 754 F.3d at 156; *Petras*, 857 F.3d at 502.

As to the UR theory, Polansky also misstates what the rule says in the first place. He alleges that the "UR Committee physicians must be members of the medical staff of the hospital." AC ¶ 104. Not so—the regulation expressly permits the use of "a group outside the institution … established in a manner approved by CMS." 42 C.F.R. § 482.30(b)(1)(ii)(B). Furthermore, Polansky has not pleaded facts showing which hospitals lacked a UR function at which time—indeed, as to Geisinger Medical Center and Community Medical Center, he has *no* allegations about UR function at all. He has not pleaded facts that give rise to a strong inference that any claims were submitted in violation of this rule, or provide specifics about when those claims were submitted and by which entities.

His theory about physician ordering is misdirection. He does not actually allege that any claims were submitted without a physician order (let alone plead specifics—the who, what, when, where, and how of such orders), but only that the Hospital Defendants violated the spirit of this rule because the doctors considered EHR's recommendations as to some patients. Indeed, his allegations are contrary to his theory: he alleges that EHR tracked treating doctors' agreement and disagreement with EHR's recommendations, AC ¶¶ 77, 150, confirming that doctors (not EHR) were the ones actually submitting the orders. Polansky's real gripe is that he thinks doctors should not consider EHR's input. But there is no rule that says so. And Polansky certainly has not pleaded specifics to identify any order ever submitted without a physician's involvement, or give rise to a strong inference that this ever happened. Moreover, he

pleads no facts to show why it is appropriate for doctors to consult the McKesson InterQual criteria (which are "widely used," AC ¶ 61) but consulting EHR's criteria violates the doctor-ordering requirement.

Finally, Polansky alleges that Defendants violated a requirement that the hospital-status order must be based on the "patient's hospital course, medical plan of care, and current condition." *Id.* ¶¶ 106–11. But Polansky himself explains that referrals to EHR were made only *after* the treating physicians expressed their professional opinions regarding whether inpatient admission was warranted. *See, e.g.*, AC ¶¶ 62-63, 67. Polansky also alleges that upon referral, EHR was provided with "clinical snapshots" and the "limited clinical information generated at the time of the patient's presentation to the hospital." AC ¶ 63.

While this theory is not fleshed out, Polansky appears to read into the regulation requirements that physicians consider more fulsome diagnostic tests and patients' response to treatment before ordering inpatient admission. But the regulation only requires that the order be based on the knowledge of "patient's hospital course, medical plan of care, and current condition." *See* 42 C.F.R. § 412.3; AC ¶ 63.

Nor has Polansky provided any details or specifics about claims where EHR supposedly evaluated a patient's status at a different time than an order was entered. He offers this theory entirely devoid of facts. At which hospital did this happen? When? How much time elapsed between when the evaluation was made and the order was

entered—and was it large enough to be material, and why? Polansky's naked allegations provide no answers, and thus fail under Rule 9(b).

2. No materiality

Not every minor or technical violation of a policy or requirement results in a false claim, punishable with treble damages and statutory damages. *Escobar*, 136 S. Ct. at 2003. Instead, there is a false claim only where the violation is material to the Government's decision whether to pay the claim. *Id.* Materiality is a separate element of every False Claims Act count, and failure to plead facts supporting it is grounds for dismissal under Rules 9(b) and 12(b)(6). *See id.* 2004 n.6; *United States ex rel. Petratos v. Genentech, Inc.*, 855 F.3d 481, 489 n.2 (3d Cir. 2017). As the Supreme Court emphasized, "False Claims Act plaintiffs must also plead their claims with plausibility and particularity under Federal Rules of Civil Procedure 8 and 9(b) by, for instance, pleading facts to support allegations of materiality." *Escobar*, 136 S. Ct. at 2004 n.6. The "materiality standard is demanding" and "rigorous." *Id.* at 2003. "Minor or insubstantial" noncompliance with a billing rule is not enough. *Id.*

Polansky has failed to meet this standard here. He has not pleaded any facts suggesting that the Government would not pay a claim for inpatient hospital care if it knew the hospital or doctor consulted with and received advice from EHR. On the contrary, the facts in the complaint and those susceptible to judicial notice show the opposite: that notwithstanding Polansky's opinions on this subject, the Government

does not consider consulting with EHR to be a material violation of any rule. The complaint should be dismissed on materiality grounds, for two reasons:

First, the allegations in this complaint and facts susceptible to judicial notice show—without any doubt—that the Government was aware of Polansky's theory that using EHR's services and methods renders hospital claims false, and aware that the Hospital Defendants used EHR's services and methods. Polansky filed the original complaint in *Polansky I* on July 26, 2012, and later amended to make express allegations about Holy Spirit's use of EHR. *See generally* Dkt. (reflecting case filing date), Dkt. 428-30. Again, the False Claims Act requires that at the time of filing a *qui tam*, a "copy of the complaint and written disclosure of substantially all material evidence and information the person possesses shall be served on the Government." 28 U.S.C. § 3730(b)(2). The Government is required by law to investigate the allegations diligently. *Id.* at § 3730(a). Furthermore, Polansky's allegations here reveal that the Government was on notice that the Hospital Defendants used EHR's products and services: throughout his complaint, Polansky notes EHR's role in handling appeals on behalf of the Hospital Defendants. *See, e.g.*, *A*C ¶¶ 155, 160. Yet despite this, Polansky has not alleged that the Government rejects these claims on the grounds that EHR was involved.

Proof of materiality includes "evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement."

Escobar, 136 S. Ct. at 2003. There are no such allegations here. If "the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were [allegedly] violated, and has signaled no change in position, that is strong evidence that the requirements are not material." *Id.* at 2003-04.

In the wake of *Escobar*, the Third Circuit has applied this standard to affirm dismissal based on the continued payment of claims or other inaction despite notice of alleged noncompliance with a contract or regulation. *See, e.g.*, *Escobar*, 136 S. Ct. at 2003; *see, e.g.*, *Petratos*, 855 F.3d at 487–90 (finding relator had not adequately pled materiality in light of Government's inaction and decision not to intervene in case after receiving "material, non-public evidence" from relator); *United States ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 763–64 (upholding a district court's grant of summary judgment upon finding that the Government knew about the alleged conduct and regularly paid the type of claims at issue). *Polansky I* and Polansky's own allegations in his complaint undermine any inference of materiality because they suggest that the Government has had knowledge of EHR's involvement with hospital admission status determinations since 2012, yet has declined to take action.

Second, the Government's actions in *Polansky I* and *Polansky II*—declining to intervene and then moving to dismiss the first case, as well as the Government's declination to intervene here—also underscores the absence of materiality. Courts have previously found "insufficient FCA materiality where the Government investigated a relator's allegations but chose not to intervene or otherwise address the defendant's

allegedly improper behavior." *Polansky I*, Dkt. 561 at 35 (citing *Cressman v. Solid Waste Services, Inc.*, No. 13-5693, 2018 WL 1693349, at *6 (E.D. Pa. Apr. 6, 2018) (noting that "the Department of Justice's declination to intervene or take any action against Defendant" was relevant to materiality inquiry); *see also Petratos*, 855 F.3d at 490 ("[T]he Department of Justice has taken no action against [Defendant] and declined to intervene in this suit."); *United States v. Sanford-Brown, Ltd.*, 840 F.3d 445, 447 (6th Cir. 2016) (affirming grant of summary judgment based on lack of materiality where the Government investigated the allegedly fraudulent conduct and "concluded that neither administrative penalties nor termination was warranted."). As to *Polansky I*, the Government's actions were even more telling: it not only declined to intervene and pursue the case itself, but it affirmatively acted to dismiss the case and prevent Polansky from pursuing it.

Accordingly, the Court should dismiss this case because (i) Polansky has not pleaded facts with specificity to show materiality, and (ii) facts that are susceptible to judicial notice undercut any notion of materiality.

3. No specifics as to two of the Hospital Defendants

The arguments above apply to all the Hospital Defendants. Here, we emphasize that the problems are especially acute as to two of the three Hospital Defendants: Geisinger Medical Center and Community Medical Center. As to them, Polansky offers almost no specifics, and certainly not enough to give rise to a strong inference that these hospitals submitted false claims.

a) Geisinger Medical Center

Polansky's allegations about Geisinger Medical Center are strikingly thin. The complete extent of his allegations about this entity are the following:

- Geisinger Medical Center became an EHR client sometime between 2010 and 2014, and it was an "enthusiastic" client (AC ¶¶ 59, 137);
- Geisinger Medical Center received reports tracking how often physicians agreed and disagreed with EHR's recommendations (AC ¶ 150); and
- Geisinger Medical Center's contract with EHR "*would have* included case referral minimums consistent with EHR's standard practice" (AC ¶ 92 (emphasis added)).

This is all there is—it is as if Polansky hoped that the Court would infer liability (or that he met his pleading burden) simply because he listed this hospital in the same complaint as Holy Spirit, and both (for a period of time) had "Geisinger" in their name.

This is not "reliable indicia that lead to a strong inference" of fraud, or enough to put Geisinger Medical Center on notice of the "precise misconduct with which they are charged." *Foglia*, 754 F.3d at 155; *Petras*, 857 F. 3d at 502. Certainly, Polansky could have made very same allegations about any EHR client. Indeed, Polansky pleads that he did not work for and does not have access to information about Geisinger Medical Center. AC ¶ 92. He acknowledges that he does not have "detailed information [about] the scope and volume of EHR services provided to Geisinger Medical Center." *Id.*

In *Polansky I*, Polansky offered more details about the hospital defendants there than these defendants here—but the court found that he flunked Rule 9(b) as to each. Dkt. 103 at 45, 47. There, the court held that "[a]llegations that could be applied to any of EHR's clients paired with two vague sets of cases EHR reviewed for [the defendant hospital] sometime in 2007 or 2008 are not sufficient" under Rule 9(b). *Id.* at 45. Here, the allegations are even weaker: Polansky offers no information at all about cases that EHR supposedly reviewed for Geisinger Medical Center. Rule 9(b) requires that the claims against Geisinger Medical Center be dismissed.

b) Community Medical Center

Polansky's allegations about Community Medical Center offer no more "reliable indica that lead to a strong inference of fraud," *Foglia,* 754 F.3d at 155, than do his allegations about Geisinger Medical Center. As to Community Medical Center, he alleges:

- Community Medical Center signed a two-year contract with EHR in March 2010, and renewed it in March 2012—i.e., outside the statute of limitations. (AC ¶ 91);
- Community Medical Center sent over 300 cases to EHR in 2010 (AC ¶ 152); and
- Of the cases that Community Medical Center asked EHR to evaluate, EHR recommended a different billing status in 73% of them (AC ¶ 16);
- Community Medical Center received reports tracking how often physicians agreed and disagreed with EHR's recommendations (AC ¶ 150);

- *Exhibit A* to the complaint is a list of cardiac stent cases where EHR recommended in-patient status, and "almost all" were billed according to that recommendation when, in Polansky's opinion, only some cardiac stent patients need in-patient treatment (AC ¶163).

The first two bullets reflect facts that could apply to any EHR client. Nothing about signing a contract with EHR or the volume of cases leads to a strong inference of fraud. That EHR recommended a different status in 73% of cases does not lead to such an inference either. Polansky does not plead facts to show that EHR's recommendations were consistently wrong, or explain how these cases were chosen—i.e., were they a random sample of case, or examples that are usually inpatients but were coded differently? As to the next point (that EHR tracked how often physicians agreed or disagreed), this is evidence that contradicts Polansky's theory: it shows that physicians could and did disagree with EHR's recommendations, and that their orders rather than EHR's recommendations would control.

Nor does *Exhibit A* show fraud—it is elementary statistical misdirection. Polansky alleges that the cases listed here are ones that are usually best suited for outpatient or observation status, but "almost all" were billed as inpatients. But this does not show fraud. Even if, for the sake of argument, only 10% of cardiac stent cases properly required inpatient care, a hospital that did 500 stent cases in a year would expect at least 50 inpatients. Listing those 50 expected cases would not prove fraud. Polansky lists only eight—and does not allege that these were a random sample. Taking

Polansky's allegations as true, the same list could be generated for any hospital that does more than a handful of these procedures.

The missing facts are conspicuous. He does not identify any people at Community Medical Center who were involved in the alleged fraud. He does not identify what or which patients were involved, but rather asserts generally that the hospital agreed with most of EHR's recommendations. AC ¶ 142. He does not allege when the fraud happened, or how EHR recommended the wrong outcome on any particular patient. He does not identify a single instance where a physician was overruled or forced to accept EHR's recommendation, or a single instance where a case was submitted without a physician's order. In short, Polansky has failed to satisfy Rule 9(b).

4. No specifics to support Polansky's "information and belief" allegations about false claims where EHR was not involved

The complaint suggests, on information and belief, that the Hospital Defendants violated the False Claims Act as to claims they submitted where EHR was not consulted, purportedly because knowing about EHR's approach somehow tainted their conduct for other patients. *See, e.g.*, AC ¶ 2; ¶ 72 (alleging that the Defendant Hospitals used EHR's "fraudulent risk-based methodology" on cases not referred to EHR.).

Polansky has offered nothing more than passing and conclusory allegations as to these non-EHR claims. He suggests that such claims are false, but for no other reason than that he says so. Polansky has not come close to satisfying Rule 9(b) in this regard. Here again, he has not provided "particular details" about non-EHR claims that give

rise to a "strong inference" that such false claims were submitted. *Foglia, LLC*, 754 F.3d at 156. Nor does he plead *anything* about the "who, what, when, where and how," *see Moore & Co., P.A.*, 812 F.3d at 307 of these claims—that is, which hospitals submitted them, when, and why they were false. Accordingly, Polansky has failed to state a claim as to any patients where EHR did not make a recommendation regarding hospital status.

5. Because the complaint fails to plead a violation of the False Claims Act, Counts II, III, and V also fail as a matter of law.

Polansky also pleads false-claims theories for creating false records (Count II), conspiracy (Count III), and retaining an overpayment (Count V). These also fail as a matter of law because he has not pleaded an underlying violation of the False Claims Act.

As to Count II, "[t]o be liable under subparagraph 3729(a)(1)(B), there must be an underlying violation of subparagraph 3729(a)(1)(A)." *United States ex rel. Creighton v. Beauty Basics Inc*, No. 2:13-CV-1989-VEH, 2016 WL 2642740, at *3 (N.D. Ala. May 10, 2016). Because Polansky fails to plead a violation of subparagraph 3729(a)(1)(A)—i.e., submission of a false claim—Count II fails as a matter of law. *See United States v. Bracco USA, Inc.*, No. 20CV8719 (EP) (JSA), 2022 WL 17959578, at *4 (D.N.J. Dec. 27, 2022) ("The only difference between a § 3729(a)(1)(A) and a § 3729(a)(1)(B) claim is that in a Section (B) claim, a plaintiff must prove the additional element that the defendant made, used, caused to be made or used, 'a false record to cause a false claim to be paid or

approved.'"); *see also* Boese & Baruch, *Civil False Claims and Qui Tam Actions* § 2.01(B) ("Liability under Section 3729(a)(1)(B) is dependent upon a violation of Section 3729(a)(1)(A) because the provision requires a false claim.").

Count III also fails, because "there can be no liability for conspiracy where there is no underlying violation of the FCA." *Petras*, 857 F.3d at 507 n.53 (quoting *Pencheng Si v. Laogai Research Found.*, 71 F.Supp.3d 73, 89 (D.D.C. 2014)).

Count V also fails. Regardless whether the complaint successfully pleads claims under 3729(a)(1)(A) and (B), Count V must be dismissed as redundant because it is premised on the same conduct as Counts I and II. *See Bracco USA, Inc.*, 2022 WL 17959578 at *7 ("[I]t is well-settled that reverse false claims may not be based on the same conduct as a plaintiff's claims under 31 U.S.C. §§ 3729(a)(1)(A) and (a)(1)(B)") (collecting cases).

VI. CONCLUSION

For the reasons above, the Court should dismiss the amended complaint. Polansky has already amended his complaint once. In all, the amended complaint is at least the sixth *qui tam* complaint Polansky has filed based on his EHR theory. As many of the grounds for dismissal could never be cured through further repleading, the Court should dismiss the case with prejudice (as to Polansky) and without leave to amend.

Respectfully submitted,

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May 28, 2024

CERTIFICATE OF SERVICE

I, Matthew L. Knowles, hereby certify that the forgoing Motion To Dismiss was served upon all counsel of record through the Court's ECF system, sent electronically to the registered participants in this matter as identified on the Notice of Electronic Filing on this 28th day of May 2024.

/s/ Matthew L. Knowles

CERTIFICATE OF WORD COUNT

I, Matthew L. Knowles, certify that according to the word count function in the software program used to prepare this brief (Microsoft Word 365), this brief contains 17,427 words, excluding the caption, tables of contents and authorities, signature block, and certifications.

Dated: May 28, 2024 */s/ Matthew L. Knowles*